electrode™

Neuroelectrics User Manual

- P2. Electrodes -

CAUTION: INVESTIGATIONAL DEVICE Limited by United States law to investigational use.

NE neuroelectrics®

Europe Office

Avinguda Tibidabo, 47 bis 08035 Barcelona, Spain Tel. +34 93 254 03 66 Fax. +34 93 212 64 45

US Office

210 Broadway, Suite 201 Cambridge, MA 02139, USA Tel. +1 617 390 6447

Email: info@neuroelectrics.com

www. neuroelectrics.com

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Manufacturer:



Neuroelectrics Barcelona SLU Avinguda Tibidabo 47, bis 08035 Barcelona

C E Spain Telephone: + 34 93 254 03 70

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About the Electrode User Manual

The **Electrode User Manual** belongs to the **Part II** of the Neuroelectrics User Manual.

The **Neuroelectrics User Manual** includes three parts:

- Part I: Enobio User Manual or Starstim User Manual
- ▶ Part II: Electrode User Manual
- ► Part III: NIC User Manual

Before you first use the Enobio/Starstim system, you should read the three parts of the Neuroelectrics User Manual. The Electrode User Manual does not discard the need of reading the Enobio/Starstim and NIC parts.

The PDF version of all parts of the Neuroelectrics User Manual can be found under the Documentation section of Neuroelectrics webpage:

www.neuroelectrics.com/documentation

Change Record

Issue	Date	Changes made
1.0	2016.02.18	Neuroelectrics User Manual: Electrode part creation
1.1	2017.02.28	NG Electrodes update
1.2	2017.05.12	Added Drytrode caution
1.3	2017.07.25	Safety warnings for stimulation & Sponstim maintenance update
1.4	2018.09.10	Solidgeltrode removed, NG geltrode updated

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I. Introduction

Currently, Neuroelectrics provides distinct types of electrodes: 10 designed by Neuroelectrics and 2 externally manufactured. The electrodes designed and manufactured by Neuroelectrics are intended to be used exclusively with Neuroelectrics devices, like Enobio or Starstim, and they are not compatible with any other commercial device.

In this manual, all the electrodes commercialized by Neuroelectrics are described. For each type of electrode, you may find the corresponding use instructions and the guidelines on how to clean and store the electrode. You will find here all types of electrodes: the standard EEG electrode to be used with conductive gel, dry electrodes that require no contact liquid, sponge stimulation electrodes to be used with saline solution, and new electrodes that use a solid form of conductive gel. Pay special attention to the

functionality of each type of electrode and always use it accordingly. In general, the electrodes can be used either for EEG monitoring, or for brain stimulation. The only exception, is our unique model named Pistim, which can be used for both techniques. Additionally, we also have three types of electrodes that can be used as the electrical reference for our devices. Finally, because you might want to combine brain stimulation with magnetic resonance imaging (MRI), we also provide MRI compatible, stimulation and reference, electrodes.

All the electrodes are compatible with the easy-insert system of the Neuroelectrics neoprene headcap and headband, both included in the Enobio and Starstim packages. All of them are compatible with the electrode cables included in the packages, except the MRI compatible electrodes which require special cables, that are

included in our MRI kits.



Geltrode. The standard EEG electrode



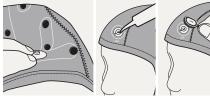
Name: GELTRODE Code: NE022 Function: EEG

The Geltrode is a wet EEG electrode that provides a rear-fill aperture for gel supply. It requires the use of the conductive electrode gel, and it can be used in scalp areas with or without hair.

Description

The Geltrode has a Ag/AgCl coated core of 12 mm diameter. It has a rear-fill aperture and the contact area is approximately 1 cm².

Use Instructions



- 1 Insert the electrode in the desired position of the neoprene cap.
- 2 Place the cap on the subject.
- 3 Use the curved syringe to inject the conductive gel through the hole on the top of the electrode.
- 4 Connect the medical sockets of the electrode cable to the electrodes inserted on the cap.

Maintenance & Durability

After each use, clean the Geltrode using a water, a tissue and a cotton swab. The conductive gel should be completely removed because it might degrade the electrode. Avoid the direct sunlight exposure and the contact with metals when the electrode is not being used. The better the Geltrode is cleaned, the longer it lasts. If properly cleaned and maintained, the Geltrode can be used, on average, 30 times. When the electrode reaches the end of its lifetime, the coating starts to wear and tear which will produce a noisier signal and consequently decrease the quality of the EEG.

NG Geltrode. The next generation gel electrode



Name: NG GELTRODE

Code: NE032 Function: EEG

Based on the next generation (NG) assembling system, the NG Geltrode is a EEG electrode that allows the access to the scalp through the headcap. It can be used wet with gel, we recommend Signa Gel® or dry with solidgel technology. The solid-gel technology is the only of its kind that uses a solidgel consumable placed into the electrode for EEG monitoring.

Description

The NG Geltrode consists of two pieces: the fastener (superior part) and the threaded washer (inferior part). The fastener is based on a Ag/AgCl sintered pellet with a 4 mm diameter. It has a rear-fill aperture and the contact area is approximately 1 cm².

Use Instructions

To be used with gel:

- 1 Insert the threaded washer in the desired position of the neoprene cap.
- 2 Place the cap on the subject.
- 3 Use the curved syringe to fill in the fastener with conductive gel.
- 4 Screw the fastener on the washer.
- 5 Connect the electrode cable connection to the fastener.

To be used with the solid consumable:

- 1 Insert the threaded washer in the desired position of the neoprene cap.
- 2 Put the cap on and use a cotton swab, after being immersed in a water and glycerin solution (1:1), to part the hair and to clear the scalp through the washer.



3 Insert the solidgel consumable inside the threaded washer.



4 Screw the fastener on the washer.



5 Connect the electrode cable connection to the fastener.

Cleaning

After each use, wash the NG Geltrode with tap water and use a tissue to complete the cleaning.

Maintenance

Avoid direct sunlight exposure and contact with metals when the electrode is not being used.

Durability

The NG Geltrode is a long lasting electrode that can be reused many times. Its intended number of uses is 100.

IV

Foretrode. The forehead EEG electrode



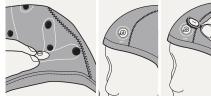
Name: FORETRODE Code: NE021 Function: EEG

The Foretrode is the ideal EEG electrode to be used on bare-skin scalp areas, like the forehead. The use of gel on the tip is optional.

Description

The Foretrode is based on a Ag/AgCl sintered pellet with an approximate area of 0.1 cm².

Use Instructions



- 1 Insert the electrode in the desired position of the neoprene cap.
- 2 Inject a small portion of conductive gel in the contact surface of the electrode (optional).
- 3 Connect the medical sockets of the electrode cable to the electrodes inserted on the cap.
- 4 Place the cap on the subject.

Maintenance & Durability

After each use, clean the Foretrode using a tissue and water. The conductive gel should be completely removed because it might degrade the electrode. Avoid direct sunlight exposure and contact with metals when the electrode is not being used. The better the Foretrode is cleaned, the longer it lasts. If properly cleaned and maintained, the Foretrode can be used approximately 100 times.

V

Drytrode. The dry EEG electrode



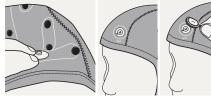
Name: DRYTRODE Code: NE023

The Drytrode is a dry EEG electrode. It does not required the application of any type of gel between the electrode and the scalp. It can be used in scalp areas with or without hair. The Drytrode was specially designed for fast applications out of the lab or requiring a gel-free experience. It is the perfect electrode when the ease of use is more important than the quality of the signal, like in BCI applications.

Description

The Drytrode is a Ag/AgCl coated electrode that provides a 10-point contact surface.

Use Instructions



- 1 Insert the electrode in the desired position of the neoprene cap.
- 2 Attach the necbox and the electrode cable to the cap, and connect one to the other.
- 3 Connect the medical sockets of the electrode cable to the electrodes inserted on the cap.
- 4 Put the cap on.

Maintenance & Durability

After each use, clean the Drytrode using a tissue. If needed, you may use water to complete the cleaning. Avoid direct sunlight exposure and contact with metals when the electrode is not being used. The Drytrode is a long lasting electrode so it can be reused many times. Its intended number of uses is 100.

CAUTION: Please make sure there is no excessive pressure or force on the head while using the Drytrode.

VI

Pistim. The hybrid tCS & EEG electrode



Name: PISTIM Code: NE024

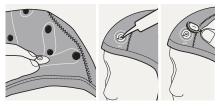
Function: EEG and Stimulation

The Pistim is a unique electrode due to its dual functionality: it works for stimulation and for EEG monitoring. Thus, it is the ideal electrode when EEG monitoring is required in a stimulation session. Further, due to its reduced size, it is perfect for focal multi-electrode stimulation experiments. Read the <u>Safety Information for Stimulation</u> chapter before using this electrode.

Description

The Pistim provides a π cm² circular contact area and a rear-fill aperture for gel supply. It is based on sintered Ag/AgCl pellet of 12 mm diameter.

Use Instructions



- 1 Insert the electrode in the desired position of the neoprene cap.
- 2 Use the curved syringe to inject conductive gel in the contact surface of the electrode.
- 3 Place the cap on the subject.

- 4 Use the curved syringe to inject more electrode gel, through the hole of the electrode.
- 5 Connect the medical sockets of the electrode cable to the electrodes previously placed on the cap.

Maintenance & Durability

After each use use a cotton swab and water to completely remove the gel from the Pistim. When the electrode is not being used, avoid direct sunlight exposure and contact with metals. Each electrode should be replaced after 10 hours of stimulation because the Ag/AgCl is expected to be consumed. Nevertheless, the time of the Ag/AgCl consumption depends on the type and intensity of the stimulation current.

VII

NG Pistim. The next generation hybdrid electrode



Name: NG PISTIM
Code: NE029
Function: FEG and Stimulation

Based on the next generation (NG) assembling system, the NG Pistim is the only hybdrid electrode that provides a clear access to the scalp, allowing good control over the impedance values. Similarly to the regular Pistim, the NG Pistim is a hybrid electrode that can be used for stimulation and for EEG monitoring. Read the Safety Information for Stimulation chapter before using this

electrode.

Description

The NG Pistim consists of two pieces: the fastener (superior part) and the threaded washer (inferior part). It provides a π cm² circular contact area. It is based on sintered Ag/AgCl pellet of 12 mm diameter.

Use Instructions

- 1 Insert the threaded washer in the desired position of the neoprene cap.
- 2 Place the cap on the subject.
- 3 Use the curved syringe to fill in the fastener with conductive gel.
- 4 Screw the fastener on the washer.
- 5 Connect the electrode cable connection to the fastener.

Maintenance & Durability

After each use use a cotton swab and water to completely remove the gel from the NG Pistim. When the electrode is not being used, avoid the direct sunlight exposure and the contact with metals. Each electrode should be replaced after 10 hours of stimulation because the Ag/AgCl is expected to be consumed. Nevertheless, the time of the Ag/AgCl consumption depends on the type and intensity of the stimulation current.

VIII

Sponstim's. The stimulation electrodes



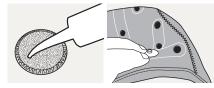
Name: SPONSTIM 25 / 8 / 5x7 Code: NE026 a / b / c

Function: Stimulation

The Sponstim's are sponge electrodes for transcranial stimulation. They are available in three different sizes and shapes. The smallest model, with a contact area of 8 cm², is ideal for multifocal stimulation experiments. The Sponstim electrodes work with saline solution, not with electrode gel. Read the <u>Safety Information for Stimulation</u> chapter before using these electrodes.

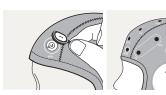
Description

The Sponstim consists of a sponge cover, a carbon rubber core and a metallic pin made of nickel plated brass. The contact surface differs among the three models: (a) circular shape with 25 cm², (b) circular shape with 8 cm², and (c) rectangular shape with 35 cm² (5 cm x 7 cm).



Use Instructions

- 1 Inject 5 ml (\approx 1/2 curved syringe) of saline solution on the yellow external surface of the sponge of each electrode.
- 2 Insert the electrodes in the desired position of the neoprene cap.
- 3 Place the cap on the subject and connect the medical sockets to the electrodes.



4 If the impedance check failed, add more saline solution on the yellow surface of the sponges by inserting the syringe through a hole of the cap near the electrode.

Maintenance & Durability

After each use, wash the sponges and rubber separately with tap water and let them dry before storage. The cleaner Sponstim is kept, the longer it lasts. When stored, make sure the metallic pins do not come into contact with the sponges, so they do not become rusty. After 100 hours of stimulation, the rubber core loses its conductive properties, and the electrode should be replaced.

IX

MRI Sponstim's. The MRI compatible stimulation electrodes



Name: MRI SPONSTIm 25 / 8 / 5x7 Code: NE026MRI a / b / c Function: Stimulation (MRI compatible)

The MRI Sponstim's correspond to the MRI compatible version of the Sponstim's. The three distinct models can be used to perform brain stimulation in a subject undergoing an MRI experiment. Similarly to the Sponstim, the MRI Sponstim electrodes require the application of saline solution. Read the <u>Safety Information for Stimulation</u> chapter before using these electrodes.

Description

The MRI Sponstim consists of a sponge cover and a carbon rubber core, both radiotranslucid materials. The contact surface differs among the three models: (a) circular shape with 25 cm², (b) circular shape with 8 cm², and (c) rectangular shape with 35 cm² (5 cm x 7 cm).

Use Instructions

The MRI Sponstim requires the use of saline solution. It can be used for bipolar or multi-channel montages. The MRI compatible electrode cables required come included with the MRI compatible kits for stimulation prepared by Neuroelectrics. The instructions to assemble the MRI compatible kits are described in the MRI Kits Manual at:

http://www.neuroelectrics.com/documentation

Maintenance & Durability

After each use, wash the sponges and rubber separately with tap water and let them dry before storage. The cleaner Sponstim is kept, the longer it lasts. After 100 hours of stimulation, the rubber core loses its conductive properties, and the electrode should be replaced.



Sticktrode. The EEG reference electrode



Name: STICKTRODE Code: NE025 Function: Reference

The Sticktrode is a disposable pregelled electrode. It is an easy-to-use adhesive electrode. When a pair is placed on the bare skin mastoid and connected to the CMS and DRL channels, it works as an electrical reference of the EEG system. Additionally, it can be used for ECG, EMG or EOG (when placed near the eye). The original manufacturer is Covidien and the code of the model is H124SG.

Description

The Sticktrode is a pre-gelled electrode with an adhesive side with non-irritating gel and a 24 mm diameter.

Use Instructions

1 Remove the adhesive cover.



2 Place the first electrode (CMS) on the mastoid and ensure there is no hair underneath.



3 Place the second electrode (DRL) inferiorly to the CMS electrode.



4 Connect the CMS and DRL cable connections to the corresponding



Maintenance & Durability

The shelf life of the electrode is 24 months when stored at 10 - 30°C temperature. The Sticktrode is a disposable, it should be used only once.

XI

MRI Sticktrode. The MRI compatible EEG reference electrode



Name: MRI STICKTRODE Code: NE025MRI Function: Reference

The MRI Sticktrode is a disposable and radiotranslucent pre-gelled electrode. It is similar to the Sticktrode and it has the advantage of being compatible with MRI (up to 7T, with any scanning sequence). Therefore, it is the reference electrode that should be used for stimulation sessions performed simultaneously with MRI. The original manufacturer is BIOPAC Systems, Inc. and the code of the model is: PK-FI 508

Description

The MRI Sticktrode is a pre-gelled electrode with a circular latex-free contact surface with 41 mm diameter. It contains a Ag/AgCI laminated core with a carbon composition contact with a 11 mm diameter.

Use Instructions

A pair of MRI Sticktrodes should be placed on the mastoid, with CMS superiorly to DRL, as described on steps 2 & 3 in the previous page.

The MRI Sticktrodes are then connected to MRI compatible electrode cables. The MRI Sticktrodes and the MRI electrode cabes are included in the MRI compatible kits for stimulation prepared by Neuroelectrics. The instructions to assemble the MRI compatible kits are described in the MRI Kits Manual at:

http://www.neuroelectrics.com/documentation

XII

Earclip. The dual reference electrode



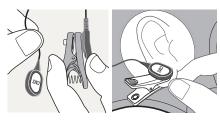
Name: EARCLIP Code: NE027 Function: Reference

The electrical reference Earclip is a dual electrode used to connect both CMS and DRL simultaneously to the same earlobe. Compared to the Sticktrode, the Earclip is a reusable alternative that offers a quick assembling process.

Description

The Earclip consists of two opposed Ag/AgCl pellets of 8 mm diameter in a clip. Each one of the two pellets has a 0.5 cm² contact surface.

Use Instructions



- 1 Connect the CMS and DRL cable connections to the Earclip.
- 2 Apply some electrode gel to the sensors (recommended).
- 3 Clip it to the right or left earlobe.

Cleaning

After each use, clean the Earclip using a tissue. If needed, you may use water to complete the cleaning.

Maintenance

Avoid direct sunlight exposure and contact with metals when the electrode is not being used.

Durability

The Earclip is a long lasting electrode so it can be reused many times. Its intended number of uses is 100.

XIII

Accessories

Curved syringe NE014



The 12 ml curved syringe is used to inject either electrode gel or saline in the electrodes

With the Geltrode and the Pistim, the curved tip of the syringe should be inserted on the small hole of the electrode to inject the electrode gel into the rear-fill aperture.

With the Sponstim's it is used to soak the yellow sponge surface.

Electrode gel 60 /250 g NE016a / NE016b



The electrode gel is a highly conductive and bacteriostatic gel. It is a water soluble, non-staining and non-gritty.

It is used for EEG monitoring electrodes and for the hybrid EEG/tCS Pistim electrodes. It is used to improve the contact between the electrode and the scalp by decreasing the impedance.

Saline solution 100 /1000 ml NE033 / NE034



The saline, or sodium chloride, solution (NaCl 0.9%) is needed to use the sponge electrodes for stimulation: Sponstim's and MRI Sponstim's.

It should be applied in the yellow external surface of the sponge. Ideally, 5 ml (half of the curved syringe) of saline solution should be enough per sponge. If the electrode impedance is not as good as desired, more solution can be added.

Glycerin solution 15 ml NE152



The glycerin solution is used to clear the scalp area before inserting the solid gel consumable in the threaded washer of the Solidgeltrode.

Use a cotton swab to apply.

Solidgel consumables NE032



The solid gel consumable is a highly conductive electrode gel in its solid form. It is used for EEG monitoring with our NG geltrode.

XIV

Silver - Silver Chloride (Ag/AgCI) Electrode Instructions

Precautions for handling the electrodes

The electrodes should not come into direct contact with metals as this may cause corrosion. Avoid touching or contaminating the bare electrode surface as dirt can increase adjustment times. Use of corrosive chemicals will damage the electrodes.

Conditioning

To minimize DC offset and drift, place the electrodes in the working position 5 minutes before starting the recording. The electrodes need some time to achieve electrochemical equilibrium with the skin and with the electrolytes of the human body.

Cleaning

The Ag/AgCl electrodes behave like sponges: they absorb water and electrode gel. The deeper these liquids penetrate the electrode, the longer it takes to them to evaporate. Corrosion will take place as a consequence and, in the long term, it will make the electrodes noisier and decrease the signal quality. Therefore, it is highly recommended to clean and let the electrodes dry immediately after use.

To clean this type of electrodes, tap water is used to rinse the gel from the electrodes. Warmed up 50 °C, the water will dissolve the gel more quickly. Only if necessary, you may use soap and/or a soft brush to remove gel residues from the electrodes. Make sure to keep the connector always dry. Let them hang to dry or use a paper towel softly. Do not let the electrodes dry without being cleaned first. When the electrodes dry while covered with gel, salt or minerals, the cleaning process becomes more difficult.

After most electrode applications, rinsing with distilled water suffices. Should the electrode surface be especially dirty or corrode, a new surface can be exposed by gently sanding off with fine sandpaper or abrading with a pumice cleanser (do not use ordinary cloth). Follow by rinsing thoroughly with running water, drying and storing to allow them to dry completely before the next use.

Disinfection

When disinfection is required, only gas or liquid agents should be used. Disinfectants containing mercury, phenols, bromine, iodine, zinc, tin, and organo-metallic compounds should be avoided. Also, the electrodes and cable insulation can not withstand steam.

Darkening

Silver chloride is light-sensitive. Exposure to light will darken the electrode surface. This will not impair the electrode performance since the large interstitial Ag/AgCl matrix is not reached by light.

Storage

The electrodes should be handled with care. They must not be stored in contact with metals, especially active metals such as iron or aluminum. Substances that could affect their electrochemical characteristics should also be avoided. Bare electrodes should be stored in a clean, dry and dark container (plastic or glass).

Malfunction

If an electrode is not operating as specified and you experience noise, then please follow the directions below concerning noisy electrodes.

Noisy electrodes

A continuously noisy electrode generally means that it has reached its end of life. You can extend the life time a little bit by using a grain 600 or higher waterproof abrasive paper to polish the electrode tip. For that, use very soft and circular movements, preferably no more than 2 or 3 times on the same area and removing an even very thin layer across the entire surface.

Life expectancy

Ag/AgCl sintered electrodes have a limited life span. This is caused by several processes such as corrosion, the dissolving of the chloride in the pellets and the wearing of the pellet during the cleaning proccess. Eventually, the color of the pellets will change from grey/ brown (AgCI) to silver (Ag) due to the loss of the chloride. The AqCl slowly dissolves in gel and water during the cleaning, which leaves only Ag behind. The resulting pure silver electrode has much higher drift and noise characteristics than the original Ag/AgCl electrode. At this point, replacement of the electrode is required.

XVI. Safety Information for stimulation

XVI.1

Safety Warnings

- If the contact impedance of a specific electrode is above $20 \text{ k}\Omega$, the corresponding channel of the Starstim will not work.
- The maximum current allowed at any channel is ± 2 mA, with a maximum potential difference of 30 V (± 15 V).
- The maximum total injected current allowed, at any time, is 4 mA.
- Based on the literature, the guideline for clinical use is to keep average current densities in electrodes below 0.06 mA/cm² (= 2 mA / 35 cm2). In this way, the stimulation
 - (= 2 mA / 35 cm2). In this way, the stimulation current densities are far from the threshold for tissue damage (14.3 mA/cm²) indicated for tDCS.
- Current densities above 0.06 mA/cm² (but always well below 14.3 mA/cm²) are for advanced clinical research or research puposes only.
- Stimulation session durations beyond

- 40 minutes are for research purposes only.
- Electrode positions above cranial foramina and fissures should be avoided because the effective current density can increase beyond safety limits in these areas.
- The Neuroelectrics stimulation electrodes should be used only with Starstim.
- Before stimulation, confirm the condition of the electrodes and check if they are clean.
- Electrodes should only be used with the conductive gels and solutions specified in this manual. Do not use other gels or solutions but those recommended in the Use Instructions.
- Perform a careful inspection of the skin under the stimulation site before and after the stimulation session. Observed adverse effects include: skin itching, tingling, headache, burning sensation, and discomfort. In rare cases, skin lesions have been observed. If any of the mentioned effects

XVI.2

Safety guide

The following chart is provided to guide operators, providing safety zones for different electrode current densities. Note this is an updated chart from 2012 version. The only change is the removal of the "Uncharted Territory" zone. Since 2013 several groups have been working with the Pistim electrode using up to 2 mA of current intensity and no ill effects have been reported.

The chart illustrates the maximum (MAX) average current density that can be used for mainstream clinical applications, advanced clinical applications, and research as function of the electrode size.

Important note

The proposed limits are not based on available negative evidence, i.e. findings of adverse effects with higher current densities. Rather, they are a conservative statement based on the limited experience with current densities

above 2 mA / 35 cm².

With regards to the use of small electrodes in tCS, it is worthwhile noting that the ratio of currrent/area (I/A) is not a good indicator of cortical electric field magnitude. For smaller electrodes more current than predicted by the I/A ratio was required to achieve a predetermined current density in the brain.

In the last few years several studies



XVI.3

Dosage

For the stimulation using Starstim, NIC software provides an informative value about the dosage of a session. The dosage is the amount of charge that the user receives during the session, and it is calculated using the equation

Dose =
$$\frac{1}{2} \sum_{n=1}^{N} \int_{0}^{T} |I_{n}(t)| dt$$

N = total number of stimulation channels

